510(k) Summary, K071961

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AUG 2 5 2008

Contact: Chris Adamcik, Associate IVD Products Manager
Prepared August 19, 2008

1. **Identification of the Device**:
   Proprietary-Trade Name: MESACUP BP180 ELISA Kit and MESACUP BP230 ELISA Kit
   Classification Name/Product Codes: DBL
   Common/Usual Name: Antibody Test Kit

2. **Equivalent legally marketed devices**: K902237 Medica (Scimedix) IIf Anti-Skin Antibody Test Kit Medica Corp.; K891098 Anti-Skin Antibody Test(Monkey Esophagus Sections Immco Diagnostics, Inc; K891099 Anti-Skin Antibody Test(Monkey/Guin Pig Esoph Sec Immco Diagnostics, Inc.

3. **Indications for Use (intended use)**: The MESACUP BP180 or BP230 TEST is a semi-quantitative enzyme-linked immunosorbent assay (ELISA) for the detection of anti BP180 or BP230 antibodies in human serum. The MESACUP TESTS are intended for in vitro diagnostic use as an aid in the diagnosis of bullous pemphigoid in conjunction with other laboratory and clinical findings. Patients with Bullous Pemphigoid are known to have either BP180 or BP230 or both types of antibodies in serum. It is recommended that each patient be tested for BP180 and BP230 antibodies.

4. **Description of the Device**: BP means Bullous pemphigoid. Bullous pemphigoid (BP) is a chronic blistering of the skin. It ranges from mildly itchy welts to severe blisters and infection, and may affect a small area of the body or be widespread. The vast majority of those affected are elderly, but it has been seen at all ages. It is an autoimmune disorder, meaning it is caused when the body's immune system malfunctions. The immune system is meant to defend the body against bacteria, viruses, and disease, but instead produces antibodies against healthy tissue, cells and organs. Some patients with BP have other autoimmune diseases such diabetes and rheumatoid arthritis. Various other factors have been reported to play a role in triggering BP. These include drugs (furosemide, penicillin's), mechanical trauma, and physical traumas (burns from radiation, sun or heat). The BP180 Elisa kit is designed to detect the BP180 protein. The related BP230 Elisa kit is designed to detect the autoantigen BP230, also known as bullous pemphigoid antigen.

5. **Safety and Effectiveness, comparison to predicate device.** The results of clinical and non-clinical testing indicates that the new device is as safe and effective as the predicate devices and methods.

6. Substantial Equivalence Chart

Characteristic	K891098 Anti-Skin Antibody Test (Monkey Esophagus Sections) Immco Diagnostics, Inc; K891099 Anti-Skin Antibody Test(Monkey/Guin Pig Esoph Sec Immco Diagnostics, Inc.	K902237 Medica (Scimedix) IIf Anti-Skin Antibody Test Kit Medica Corp.; (Now Scimedix)	MESACUP BP180 ELISA Kit and MESACUP BP230 ELISA Kit
Indications	An indirect immunofluorescence antibody test for the detection and quantitation of anti-skin (anti-intercellular and anti-basement membrane) antibodies in human serum.	The in vitro detection of skin antibodies by the indirect immunofluorescent technique has been established as an aid in the diagnosis of skin and systemic diseases. Monkey esophagus is used for the detection of both basement membrane antibodies and intercellular substance antibodies. The detection of the basement membrane antibody has been associated with the presence of a variety of bullous pamphigoid audoimmune disorders of the skin.	The MESACUP BP180 and MESACUP BP230 is intended for in vitro diagnostic use as an aid in the diagnosis of bullous pemphigoid.
Technology	Indirect immunofluorescence	Indirect immunofluorescence	ELISA
Detect what?	Anti-intercellular antibodies and anti-basement membrane antibodies.	Ani-intercellular antibodies and anti-basement membrane antibodies.	Anti BP180 Antibodies And Anti BP230 Antibodies
Disease	Pemphigus Vulgaris; Pemphigus Foliaceus Pemphigoid/EBA	Multiple anti-immune diseases, systemic rheumatic disease	Bullous Pemphigoid
Test fluid	Serum	Serum	Serum
USE	IVD	IVD	IVD

7. Conclusion

After analyzing clinical and non-clinical testing data, it is the conclusion of MBL INTERNATIONAL CORPORATION that the MESACUP BP180 ELISA Kits and MESACUP BP230 ELISA Kits are comparably safe and effective as the predicate devices, and have similar indications thus rendering them substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MBL International Corporation
C/O Daniel Kamm
Kamm & Associates
PO Box 7007
Deerfield, Illinois 60015

AUG 25 2008

Re: k071961
Trade/Device Name: Models BP180 and BP230 Elisa Kits
Regulation Number: 21 CFR 866.5660
Regulation Name: Multiple Autoantibodies Immunological Test System
Regulatory Class: Class II
Product Code: OEG
Dated: July 8, 2007
Received: July 24, 2007

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Maria Chan, Ph.D.
Acting Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):K071961

Device Name: MESACUP BP180 ELISA Kit and MESACUP BP230 ELISA Kit

Indications For Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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